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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,696	08/08/2006	Friedbert Wechs	2037.8	9927

7590 08/14/2009  
Scott E Hanf  
Hammer and Hanf  
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Charlotte, NC 28226

EXAMINER
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CHRISTIAN, MARJORIE ELLEN

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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08/14/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,696	<b>Applicant(s)</b> WECHS ET AL.	
	<b>Examiner</b> MARJORIE CHRISTIAN	<b>Art Unit</b> 1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4/27/2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-20 is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed 4/27/2009 has been entered and fully considered.
2. The rejections under 35 USC § 112 are withdrawn in light of Applicant's amendments.
3. Claims 1-20 are pending and have been fully considered.

### *Double Patenting*

4. Claims 1-9, 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/588,695. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claim 1 has an ultrafiltration rate in albumin solution in the range of 5 to 23.5 ml/(h.m<sup>2</sup>.mmHg) , whereas the copending claim 1 has an ultrafiltration rate in the range of 25 to 60 ml/(h.m<sup>2</sup>.mmHg). However, it appears that the apparatus in the instant claims would function at a higher ultrafiltration rate as there is no structural difference between the membranes. The sieving coefficient of cytochrome c in the instant claim 1 is expressed by a relation, whereas the copending claims discloses the sieving coefficient of cytochrome c as a minimum of 0.8. Using the ultrafiltration rate range disclosed by the copending claim 1, the relation disclosed by the instant claim 1 was satisfied in that it is higher 0.8. As further evidence that the copending and instant claims overlap in scope, and therefore are not patentably distinguishable, the instant specification discloses that

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the minimum sieving coefficient for cytochrome c is preferably 0.8 (Page 11, Lines 1-2).

Therefore the sieving coefficient disclosed by the copending application claim 1 are within range of the relation disclosed in the instant claim 1. Instant claims 3-9 are identical to copending claims 2-10.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The terminal disclaimer has not been entered. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

### ***Claim Rejections - 35 USC § 102***

5. **Claims 1, 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by SLUMA et al. US Patent No. 5,290,448 (hereinafter SLUMA).**

As to Claims 1, 9, 11, SLUMA discloses a semi-permeable membrane in the form of a hollow fiber (Abstract) comprising: a synthetic first polymer possessing an open-pored integrally asymmetric structure across its wall (Figures 2-5); the skin has a thickness of 0.1 to 0.2 microns on the inside of the cavity (SLUMA, Claim 3) [**porous separating layer of thickness between 0.1 and 2  $\mu$ m on the inner surface facing the lumen**]; an ultrafiltration rate in albumin solution of 13 mL/(m<sup>2</sup>.h.mmHg) (Example 3); and the albumin screen coefficient is 0 (Example 3) [**maximum sieving coefficient for albumin of 0.003**]. The limitation “where no additives are present and properties

were measured after drying” is only a caveat and does not structurally differentiate the apparatus, further the apparatus has the desired sieving co-efficient even in the presence of these additives (Example 1, C4/L13-14) ***[in absence of additives stabilizing the pores in the membrane wall and after prior drying]***. The screen coefficient in Example 3 satisfies the relation for the sieving coefficient of cytochrome c shown below.

$$SC_{cc} \geq 5 \cdot 10^{-5} \cdot UFR_{Alb}^3 - 0.004 \cdot UFR_{Alb}^2 + 0.1081 \cdot UFR_{Alb} - 0.12$$

As to Claim 10, SLUMA discloses that a polyelectrolyte with negative fixed charges is physically bound in the separating layer (C2/L62-64).

### ***Claim Rejections - 35 USC § 102/103***

6. **Claims 1-9, 11, are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent No. 6,565,782, WANG et al. (hereinafter WANG).**

As to Claims 1-9, 11, WANG discloses a hydrophilic, water-wettable, semi-permeable hollow-fiber membrane for blood purification (Abstract) comprising a synthetic first polymer (Example 1), the hollow-fiber membrane possessing an open-pored integrally asymmetric structure across its wall (Abstract, Figs. 1A-C), a porous separating layer and an open-pored supporting layer adjoining the separating layer (C3/L14-31) characterized in that there is an absence of additives stabilizing the pores in the membrane wall and after prior drying (Example 1). WANG does not appear to expressly disclose that the skin has a thickness of 0.1 to 2 microns, ultrafiltration rate

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in albumin solution, maximum sieving co-efficient of albumin and relation for the sieving coefficient of cytochrome c. However, WANG discloses a hollow fiber made of the same material, polysulfone and polyvinylpyrrolidone (C7/L51-57) (instant Claims 3-7); supporting layer that extends from the separating layer across essentially the entire wall of the hollow-fiber membrane (C3/L13-31) and has a sponge-like structure that is free from finger pores (Fig. 1C, 2A) (instant Claims 8); and similar process of making (WANG, Example 1, Claim 1). It is therefore inherent that the hollow fiber has an ultrafiltration rate in albumin solution of 10 to 23.5 ml/(h.m<sup>2</sup>.mmHg), maximum sieving coefficient for albumin of 0.003, and sieving coefficient for cytochrome c satisfies the relation (shown below), absent evidence to the contrary.

$$SC_{cc} \geq 5 \cdot 10^{-5} \cdot UFR_{Alb}^3 - 0.004 \cdot UFR_{Alb}^2 + 0.1081 \cdot UFR_{Alb} - 0.12$$

### ***Claim Rejections - 35 USC § 103***

7. **Claims 3-8 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 5,290,448 SLUMA et al. (hereinafter SLUMA) in view of US Patent No. 4,906,375, HEILLMAN (hereinafter HEILMANN).**

As to Claims 3-8, SLUMA discloses the semi-permeable membrane in the form of a hollow as shown above in the 102(b) rejection of Claim 1. SLUMA does not appear to expressly disclose the use of hydrophobic and hydrophilic polymers. However, HEILMANN discloses that the microporous hollow fiber is made up of a first hydrophobic polymer and second hydrophilic polymer (Abstract) specifically polysulfone (C4/L44-46 and polyvinylpyrrolidone (C5/L17-18) and that next to microporous barrier

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layer on the outside is a foam-like supporting structure that is different to the lamellae-like structures of the prior art (C9/L51-54) **[supporting layer extends from the separating layer across essentially the entire wall of the hollow-fiber membrane and has a sponge-like structure that is free from finger pores]**.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the hollow fiber of SLUMA to include the hydrophilic and hydrophobic polymers of HEILMANN. The motivation would have been to have a hollow fiber with very good hydraulic permeability and excellent mechanical strength (HEILMANN, C3/L55-57). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

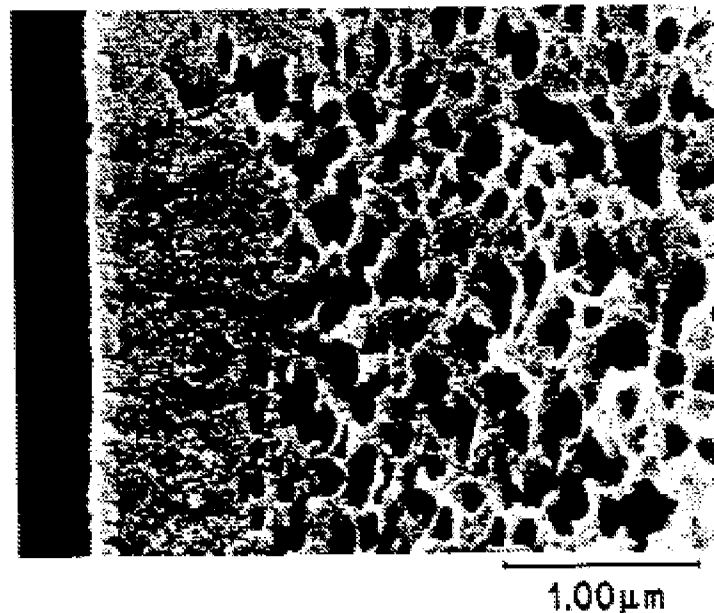
8. Applicant's arguments filed 4/27/2009 have been fully considered but they are not persuasive.

Applicant argues that "in the absence of additives stabilizing the pores in the membrane wall and after prior drying" means that it is necessary that glycerol is not present. This is not what the limitation indicates, instead it indicates an additive is not necessary, it does not exclude an additive. Further, the conditions required to meet the relation limitation can easily be manipulated during routine operation of the apparatus by a person having ordinary skill in the art based on a multitude of factors (e.g., type of fluid filtered, material used in filter, thickness of material, etc.). Additional possible structural and operational limitations can be envisaged based on this characteristic and

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therefore many hollow fiber membranes would appear to meet the conditions set by the relation and the apparatus is inherently capable of meeting the limitations of the relation.

Applicant argues that the SLUMA does not teach “an integrally asymmetric membrane” which Applicant interprets to mean “a membrane with a separating layer and supporting layer being formed together during production of the membrane”. The method of producing a membrane is not germane to the issue of patentability of an apparatus and further is not claimed. Additionally, the membrane is integrally asymmetric with supporting and separating layer as shown in Fig. 2 below.



Applicant argues that WANG does not anticipate or render obvious the claimed invention as it does not inherently meet the limitations of the relation. However, as previously stated the conditions required to meet the relation limitation can easily be manipulated during routine operation of the apparatus by a person having ordinary skill in the art based on a multitude of factors (e.g., type of fluid filtered, material used in

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filter, thickness of material, etc.) and therefore the apparatus is inherently capable of meeting the limitations of the relation.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Upon further consideration, a rejection has been made of Claim 10, and therefore the notice of allowable subject matter relating thereto has been removed.

### ***Allowable Subject Matter***

9. Claims 12-20 are allowed. The combination of a polyelectrolyte as the interior filler in the steps of producing a hollow fiber with a sieving coefficient for cytochrome c that satisfies the relation specified is novel.

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is

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(571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/  
Primary Examiner, Art Unit 1797

MC